UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

IN RE NAMENDA DIRECT PURCHASER ANTITRUST LITIGATION

Case No. 1:15-cv-07488-CM-RWL

THIS DOCUMENT RELATES TO: All Direct Purchaser Actions

PLAINTIFFS' OPPOSITION TO FOREST'S MOTION IN LIMINE NO. 12 SEEKING TO PRECLUDE PLAINTIFFS' EXPERT DR. HERRMANN FROM USING A CLAIM CONSTRUCTION CONTRARY TO THE SETTLED CLAIM CONSTRUCTION OF THE PATENT COURT

TABLE OF CONTENTS

1.	BAC	KGROUND ON THE 1/03 PATENT	. I
	A.	The Original and Reexamined Claims	. 1
	B.	The Patent Court's Claim Construction for "Effective Amount"	. 3
	C.	Forest's and Plaintiffs' Experts Agree That the Patent Court's Claim Construction Requires a "Therapeutic Effect"	. 4
II.	ARGUMENT6		
	A.	Dr. Herrmann Faithfully Applied the Patent Court's Construction of "Effective Amount"	. 6
		1. Paragraph 73 and 74 of Dr. Herrmann's Report	. 7
		2. Dr. Herrmann's Deposition	10
	B.	Forest's Motion Is an Untimely Daubert Motion	14
III.	CON	CLUSION	14

TABLE OF AUTHORITIES

Cases

Hart v. BHH, LLC 2019 WL 1494027 (S.D.N.Y. Apr. 4, 2019)	14
Medtronic, Inc. v. Guidant Corp. 465 F.3d 1360 (Fed. Cir. 2006)	3
Predicate Logic, Inc. v. Distributive Software, Inc. 544 F.3d 1298 (Fed. Cir. 2008)	2
Source Search Techs., LLC v. Lendingtree, LLC 588 F.3d 106 (Fed. Cir. 2009)	12
United States v. Teva Pharm. USA, Inc. 2019 WL 1245656 (S.D.N.Y. Feb. 27, 2019)	

Plaintiffs respectfully request that this Court deny Forest's motion *in limine* No. 12 ("MIL No. 12") (ECF No. 787) because none of Dr. Herrmann's opinions "contradicts the claim construction in the underlying patent litigation." Defs.' Br. at 1 (ECF No. 788). First, Forest's arguments misrepresent both Dr. Herrmann's opinions and also the claim construction proceedings in the patent court. Most strikingly, Dr. Herrmann's application of the patent court's construction of "effective amount" not only is perfectly logical, but also comports with Forest's own expert's understanding of the patent court's claim construction. None of Dr. Herrmann's opinions contradicts, or is even in tension with, the patent court's claim construction. Second, Forest's motion *in limine* is in reality an improper and untimely *Daubert* challenge asserting that Dr. Herrmann's opinions do not fit the facts of this case. Indeed, Forest admits as much by repeatedly citing Federal Rule of Evidence 702 in support of its supposed "motion *in limine*." Forest's motion should be denied.

I. BACKGROUND ON THE '703 PATENT

To expose Forest's sophistry, it is important to provide some background on the '703 Patent, the patent court's claim construction, and the agreements between Forest's and Plaintiffs' experts as to how those claim constructions should be understood and applied.

A. The Original and Reexamined Claims

As originally issued, the '703 Patent contained one independent claim and twelve dependent claims. Independent claim 1 recited:

1. A method for the prevention or treatment of cerebral ischemia comprising the step of administering, to a patient in need thereof, an effective amount of [a member of a class of chemical compounds that includes memantine] or a pharmaceutically-acceptable salt thereof.

Declaration of Joe Opper ("Opper Decl.") Ex. 34, PX-0373, '703 Patent, at 8, col. 13:50-55 (emphasis added). The term "effective amount" necessarily referred to the claim preamble (*i.e.*,

a "method for the prevention or treatment of cerebral ischemia") because there is literally nothing else in the claim to which it could refer. It is axiomatic that each of the dependent claims incorporated the same requirement – namely, "administering . . . an effective amount" for the "prevention or treatment of cerebral ischemia." 35 U.S.C. § 112 ¶ 4 (2000).

During a reexamination proceeding, Forest both amended its existing claims and added new claims. Reexamined claim 1 is representative for purposes of the issue Forest raises in MIL No. 12. Reexamined claim 1 recites:

1. A method for the prevention or treatment of cerebral ischemia comprising the step of <u>orally</u> administering, to a patient <u>diagnosed with</u> <u>Alzheimer's disease and</u> in need thereof, an <u>effective amount</u> of [a member of a class of chemical compounds that includes memantine] or a pharmaceutically-acceptable salt thereof.

Opper Decl. Ex. 34, PX-373, '703 Patent, at 12, col. 1:26-30 (amendment from the original underlined). As a result of the modifications, when viewed in a vacuum, "effective amount" could refer either to "the prevention or treatment of cerebral ischemia" (as in the originally-issued claim) or to the treatment of "Alzheimer's disease" (as recited in the newly-added language).

Although in a vacuum, the term referenced by "effective amount" was ambiguous, as a legal matter the reexamined claims could only be valid if "effective amount" referred to "the prevention or treatment of cerebral ischemia." This is so because "[n]o proposed amended or new claim enlarging the scope of a claim of the patent will be permitted in a reexamination proceeding." 35 U.S.C. § 305. "Claims that are impermissibly broadened during reexamination are invalid, and 'a violation of 35 U.S.C. § 305 is an invalidity defense in a patent infringement action." *Predicate Logic, Inc. v. Distributive Software, Inc.*, 544 F.3d 1298, 1302 (Fed. Cir. 2008). And a patent claim "is broader in scope than the original claims if it contains within its

scope *any conceivable apparatus or process* which would not have infringed the original patent." *Medtronic, Inc. v. Guidant Corp.*, 465 F.3d 1360, 1374 (Fed. Cir. 2006) (emphasis added); *Predicate Logic*, 544 F.3d at 1303. Because each of the original claims indisputably required "administering . . . an effective amount" for "the prevention or treatment of cerebral ischemia," the reexamined claims would have been invalid for improper broadening if they did not incorporate that same requirement.

B. The Patent Court's Claim Construction for "Effective Amount"

During claim construction, Forest and the generic defendants proposed different constructions for the term "effective amount": (1) Forest proposed "an amount shown to cause improvement in comparison to placebo treatment"; and (2) the generic defendants proposed "an amount that is therapeutically effective." Opper Decl. Ex. 35, PX-1401 (Generics' Claim Construction Brief), at 34. Forest argued to the patent court that merely requiring a "therapeutically effective" amount was "highly ambiguous" and that Forest's "proposed construction provide[d] a concrete standard by which efficacy may be judged (*i.e.*, in comparison to placebo)," thereby "eliminat[ing] the inherent ambiguities" in the generic defendants' proposed construction. Opper Decl. Ex. 36, Forest's Answering Claim Construction Brief, at 35-36.

Although the patent court ultimately adopted Forest's proposed construction, it never "rejected" the proposition that the claims require a "therapeutic effect" as Forest contends (Defs.' Br. at 3). Rather, the patent court instead agreed with Forest that requiring a "therapeutic effect" was "insufficiently precise to be helpful." Opper Decl. Ex. 37, Claim Construction Report and Recommendation, at 27. Accordingly, and consistent with Forest's request, it held that "effective amount" required a more precisely defined degree of "improvement" (*i.e.*, one "shown" in a placebo-controlled study). *Id.* at 33. Notably, nothing in the patent court's

construction (1) provides any specific definition for the "improvement" aspect of the patent court's construction of "effective amount"; or (2) addresses whether "effective amount" referred to "the prevention or treatment of cerebral ischemia" or to the treatment of "Alzheimer's disease."

C. Forest's and Plaintiffs' Experts Agree That the Patent Court's Claim Construction Requires a "Therapeutic Effect"

Forest's expert Dr. Farlow and Plaintiffs' expert Dr. Herrmann both reached the conclusion that the patent court's claim construction of "effective amount" requires a "therapeutic effect" (or "therapeutic[] benefit[]") by virtue of the inclusion of the term "improvement." Specifically, Forest's expert Dr. Farlow testified that the meaning of "improvement" in the construction of "effective amount" requires a "therapeutic[] benefit[]":

- Q. And what do you understand the word "improvement" to refer to in the court's claim construction?
- A. That a patient is *therapeutically benefited*, has improvement, and has been demonstrated by evidence-based trials in global performance, cognition, and functioning activities of daily living, but that's my -- the -- the language of just improvement, I think, means is clinically beneficial. . . .

Opper Decl. Ex. 38, Farlow Dep. at 94:12-22 (emphasis added). Likewise, Dr. Herrmann also reached the conclusion that the term "improvement" in the patent court's construction of "effective amount" required a "therapeutic effect." Lancaster Decl. Ex. 1, Herrmann Dep., at 47:8-21. Thus, the experts in this case agree that a requirement for a "therapeutic effect" (or "therapeutic[] benefit[]") emanates directly from – and clearly, therefore does not contradict – the patent court's construction for "effective amount."

Even if the term "effective amount" did not require a "therapeutic effect," the parties' experts also agree that other terms in the '703 Patent claims require a "therapeutic effect." As

Dr. Herrmann explained in his report, the claim preambles are directed to "prevention" or "treatment" of medical conditions and therefore necessarily require a "therapeutic effect":

.... Forest failed to satisfy its burden of proving that the administration of Mylan's generic version of Namenda to a patient according to Mylan's package insert would directly infringe the asserted claims of the '703 Patent by performing a method for (1) "the prevention or treatment of cerebral ischemia (original and reexamined claims 1-13); (2) the "treatment of cerebral ischemia" (reexamined claims 14-16); or (3) the "treatment of imbalance of neuronal stimulation after Alzheimer's disease" (reexamined claims 17-19). These claim terms (as interpreted by the patent court) require that the administration of memantine hydrochloride to patients per Mylan's package insert instructions achieves therapeutic effects through antagonism of NMDA receptors.

Opper Decl. Ex. 27, Herrmann Rpt. ¶ 33 (emphasis added). Forest has not challenged Dr. Herrmann's conclusion in this regard. Moreover, Forest's expert Dr. Farlow likewise agrees with Dr. Herrmann that "to treat or prevent" a medical condition requires a "therapeutic effect":

- Q. In order to treat or prevent a medical condition, would you agree that a drug must have a therapeutic effect?
- A. It's almost definitional, but, yes.

Opper Decl. Ex. 38, Farlow Dep. at 13:9-12. Thus, for multiple reasons, the experts on both sides agree that multiple terms in the '703 Patent claims, as construed by the patent court, require a "therapeutic effect," and that more specifically the term "improvement" in the construction of "effective amount" requires a "therapeutic effect" (or "therapeutic[] benefit[]").

Forest's expert also incorporated a requirement for a "therapeutic effect" in both his infringement and validity analyses. Dr. Farlow acknowledged that infringement requires that memantine achieve a "therapeutic effect" and that he planned to so testify:

Had the patent case progressed to trial, *I would have testified that memantine provides therapeutic effect due to its NMDA receptor antagonism*. I understand that Dr. Doody and Dr. Malinow – both prominent and well-respected experts in the field of Alzheimer's disease – would have expressed the same opinion. Memantine acts as an NMDA receptor antagonist. Even Mylan's experts in the Namenda® patent case agreed that memantine is an NMDA receptor antagonist.

Opper Decl. Ex. 39, Farlow 2017 Rpt., ¶ 45 (emphasis added). And regarding invalidity, when asked why the prior art does not invalidate the claims, Dr. Farlow relied upon the fact that the claims require a "therapeutic effect" and that the prior art purportedly did not teach that "therapeutic effect":

- Q. And is it your opinion that the prior use of Akatinol in Germany before 1989 is not invalidating of claim 1 of the '703 patent because you're not aware of any specific patient that was diagnosed with Alzheimer's disease and was given memantine?
- A. I'm not aware of any specific patient or specific study where patients were diagnosed with Alzheimer's disease were treated with oral memantine and demonstrated to have a *beneficial therapeutic effect* prior to April of 1989.

Opper Decl. Ex. 38, Farlow Dep., at 210:13-25 (emphasis added and objection omitted).

II. ARGUMENT

A. Dr. Herrmann Faithfully Applied the Patent Court's Construction of "Effective Amount"

Nothing in Dr. Herrmann's report or deposition suggests that he intends to deviate in any respect from the patent court's construction of "effective amount." To the contrary, his report states explicitly:

Because I understand that claim construction is a legal issue decided by a judge, I am simply accepting the patent court's claim interpretations and applying them for purposes of my infringement analysis.

Opper Decl. Ex. 27, Herrmann Rpt., ¶ 32. He specifically *quotes* the patent court's claim construction for "effective amount" four times. *Id.* ¶¶ 31, 34, 73, 83. And, when he conducted his infringement analysis, he plugged that *verbatim* construction into the claim language when assessing infringement. *Id.* ¶ 78.

Forest's key gripe seems to be that Dr. Herrmann improperly reads a requirement for a "therapeutic effect" into the patent court's construction of "effective amount." Three simple,

indisputable facts should eliminate any need for the Court to expend resources on Forest's motion. First, Forest's own expert reached the same conclusion as Dr. Herrmann – namely, that the term "improvement" in the patent court's construction of "effective amount" requires a "therapeutic" effect or benefit – rendering Forest's motion baseless. Opper Decl. Ex. 38, Farlow Dep. at 94:12-22. Second, the fact that Forest's own expert relies on a "therapeutic effect" in his infringement and validity analyses renders Forest's motion baseless. Opper Decl. Ex. 39, Farlow 2017 Rpt., ¶ 45; Opper Decl. Ex. 38, Farlow Dep., at 210:13-25. Third, because Forest does not challenge Dr. Herrmann's opinion that the patent claims' preamble language independently creates a requirement for a "therapeutic effect," Forest's motion is also moot. This is particularly so given that Forest's expert Dr. Farlow agrees with Dr. Herrmann on this issue as well. Opper Decl. Ex. 38, Farlow Dep. at 13:9-12. Nevertheless, Plaintiffs will address Forest's specific citations to Dr. Herrmann's report and deposition.

1. Paragraph 73 and 74 of Dr. Herrmann's Report

Forest asks the Court to "[c]ompare" the patent court's claim construction for "effective amount" with paragraph 73 of Dr. Herrmann's report, which purportedly "read[s] limitations into the claim term 'effective amount' that the patent court refused to adopt." Defs.' Br. at 2. Dr. Herrmann did nothing of the sort. Instead, paragraph 73 simply explains the dispute that existed between Forest's and Mylan's experts in the underlying patent litigation:

73. As discussed above, the patent court in the Namenda Patent Litigation interpreted "effective amount" to mean "an amount shown to cause improvement, in comparison to placebo." However, that construction did not specify *what* specifically was required to be improved. During the patent litigation, the dispute between the experts pertaining to the '703 Patent claims after claim construction related to whether the "improvement" referred to in the "effective amount" related to (1) the treatment of Alzheimer's disease generally or (2) the prevention or treatment of cerebral ischemia:

Dr. Doody's Opinion (¶ 30)

"Based on the Court's construction, I understand ['effective amount'] to mean an 'amount shown to cause improvement, in comparison to placebo.' (Claim Construction Order at ¶ 9.) In my opinion, this element requires patients being treated for Alzheimer's disease with memantine (or another compound covered by the claim) to be advantaged in comparison to patients receiving a placebo."

Dr. Olney's Opinion (¶ 65)

"My understanding is that the term 'an effective amount of' does not refer to an amount of memantine or other compound to treat AD patients, but instead refers to 'an amount shown to cause improvement, in comparison to placebo' to 'prevent or treat cerebral ischemia,' *i.e.* to prevent 'an imbalance of neuronal stimulation mechanisms' or to provide 'an antagonistic intervention with regard to the N-methyl-D-aspartate (NMDA) receptor channels.""

In other words, Forest's expert Dr. Doody viewed an "effective amount" as an amount "shown" to "advantage[]" Alzheimer's patients in some respect(s) relative to placebo, *irrespective of whether* it was shown to achieve that "advantage[]" though a particular mechanism of action. In contrast, Mylan's expert Dr. Olney viewed an "effective amount" as an amount "shown" to cause improvement relative to placebo in preventing or treating cerebral ischemia or in providing an antagonistic intervention with regard to the N-methyl-D-aspartate (NMDA) receptor channels.

Opper Decl. Ex. 27, Herrmann Rpt. ¶ 73 (emphases in original). Forest's Brief never identifies which limitation Dr. Herrmann supposedly "read[s]" into the "effective amount" in paragraph 73.

For several reasons, paragraph 73 of Dr. Herrmann's report cannot possibly be in conflict with the patent court's claim construction. First, given that Dr. Herrmann quoted the patent court's claim construction verbatim and then only identified the dispute between the experts in the Namenda patent litigation, it is unclear what limitation Dr. Herrmann is supposedly "reading" into the claim. Second, to the extent Forest is actually complaining about the expert opinion of Mylan's expert, Dr. Olney, there is no doubt that Dr. Olney would have offered that opinion at trial. Indeed, Forest specifically chose not to seek to exclude Dr. Olney's opinion

prior to trial. Opper Decl. Ex. 40, PX-0349, Forest's Position on Mylan's Expert Witnesses in the Namenda Pretrial Order, at MNAT_0000107 ("[Forest] maintain[s] that any objections to experts should be done through cross-examination at trial, and that the Court can resolve any objections as it deems appropriate at that time."). Thus, Forest's argument that this argument "could not have been advanced by Mylan at the patent trial" (Defs.' Br. at 2) is flatly incorrect. Third, and perhaps most tellingly, the key phrase Forest argues was "rejected" by the patent court – *i.e.*, "therapeutic effect" – is not even mentioned in paragraph 73 of Dr. Herrmann's report.

Forest also complains about paragraph 74 of Dr. Herrmann's report, which states:

74. In my opinion, for the reasons explained below, the term "effective amount" refers to the recited *therapeutic process* in each of the independent claims – namely, (1) the "prevention or treatment of cerebral ischemia" (original and reexamined claims 1-13); (2) the "treatment of cerebral ischemia" (reexamined claims 14-16); or (3) "treatment of an imbalance of neuronal stimulation after Alzheimer's disease" (reexamined claim 17-19). In other words, I agree with Dr. Olney.

Opper Decl. Ex. 27, Herrmann Rpt. ¶ 74 (emphasis in Forest's Brief). As an initial matter, paragraph 74 in no way contradicts the court's construction of "effective amount"; it simply states Dr. Herrmann's opinion that the term – precisely as it was construed by the patent court – refers to the claim preamble (*e.g.*, the "prevention or treatment of cerebral ischemia") rather than the term "patient diagnosed with Alzheimer's disease" in the body of the claims. This is the very same opinion offered by Mylan's expert, Dr. Olney, in the patent litigation. And, as explained, there is no doubt that this opinion (1) does not conflict with the patent court's claim construction; and (2) was going to be offered at the trial in the patent litigation.

Forest's motion is predicated on the words "effective amount" referring to Alzheimer's disease rather than the claim preambles, but Forest has identified absolutely nothing in the patent

court's claim construction to support its position. Indeed, even Forest's own expert agrees with Dr. Herrmann and Dr. Olney, not Forest. Opper Decl. Ex. 38, Farlow Dep., at 95:14-19. Based on Forest's emphasis (in bold italics), it appears that Forest is inarticulately suggesting that Dr. Herrmann's reference to a "therapeutic process" in paragraph 74 improperly incorporates into "effective amount" the concept of a "therapeutic effect," a concept that the patent court purportedly "rejected" (Defs.' Br. at 3). For several reasons, Forest is demonstrably wrong. First, the term "therapeutic process" in paragraph 74 does not even relate to "effective amount"; rather, as the context of the sentence makes clear, it is the shorthand that Dr. Herrmann uses for the preambles in the three independent claims (*i.e.*, the "prevention or treatment of cerebral ischemia," the "treatment of cerebral ischemia," and the "treatment of an imbalance of neuronal stimulation after Alzheimer's disease").

Second, even if "therapeutic process" in paragraph 73 referred to "effective amount" rather than the claim preambles – and clearly it does not – the supposedly rejected claim construction for "effective amount" was a "therapeutic effect" rather than a "therapeutic process." Forest never even attempts to explain why "therapeutic process" contravenes the patent court's claim construction. Moreover, as explained *supra*, the patent court never held that "effective amount" does not require a "therapeutic effect," and indeed Forest's expert Dr. Farlow understands the term "improvement" in the construction for "effective amount" to require that a patient be "therapeutically benefited" (Opper Decl. Ex. 38, Farlow Dep. at 94:12-22), a specific type of "therapeutic effect."

2. Dr. Herrmann's Deposition

None of Forest's citations to Dr. Herrmann's deposition reflects any deviation from the patent court's claim construction.

a) Deposition Page 39

Forest cites to page 39 of Dr. Herrmann's transcript for the proposition that "Dr. Herrmann admitted that this is simply his opinion of how the term [presumably, 'effective amount'] should have been construed by the court." Defs.' Br. at 5. But Forest's citation is both nonsensical and disingenuous. Forest cites lines 6-11 of page 39 but has excised pages 37-38 from its exhibit. As the pages Forest excised makes clear, Dr. Herrmann's cited testimony does not even relate to "effective amount"; rather it refers to the claim preambles addressed in paragraph 33 of Dr. Herrmann's report. Opper Decl. Ex. 28, Herrmann Dep., at 37:14-39:11. It is beyond the pale for Forest to excise the preceding testimony on pages 37-38 of Dr. Herrmann's transcript but then make an argument it could not have made had it disclosed the excised testimony.

b) Deposition Page 49

Forest complains that Dr. Herrmann testified that "if you are treating an *Alzheimer's disease* patient with this medication, you would be *expecting a therapeutic effect*." Defs.' Br. at 5 (emphasis added). First, Forest's citation does not even implicate the term "effective amount." Indeed, Dr. Herrmann was being questioned about a completely different claim limitation: "treatment of imbalance of neuronal stimulation after Alzheimer's disease." Lancaster Decl. Ex. 1, Herrmann Dep., at 48:2-49:22. Second, Forest's own expert agrees with Dr. Herrmann that "treat[ing]" a medical condition like Alzheimer's disease requires a "therapeutic effect." Farlow Dep. at 13:9-12. Third, even if Dr. Herrmann was referring to the term "effective amount," the experts all agree that the concept of "improvement" in "effective amount" implicates a therapeutic effect. Opper Decl. Ex. 38, Farlow Dep. at 94:12-22. Thus, Forest cannot possibly complain about Dr. Herrmann's testimony in this regard.

c) Deposition Pages 47-55

Forest also cites to pages 47-55 of Dr. Herrmann's transcript. Yet again, Forest's brief is rife with misrepresentation. First, the testimony quoted by Forest in the parenthetical does not even relate to the claim term "effective amount" but rather refers to the claim term "treatment of imbalance of neuronal stimulation after Alzheimer's disease." Lancaster Decl. Ex. 1, Herrmann Dep., at 52:21-53:25. This distinction is important because, as Dr. Herrmann's report makes clear, the requirement for a "therapeutic effect" stems primarily from the preamble language. Opper Decl. Ex. 27, Herrmann Rpt. ¶ 33. Second, as explained above, Forest's own expert has agreed that the claims required a "therapeutic effect due to [] NMDA receptor antagonism." Opper Decl. Ex. 39, Farlow 2017 Rpt., ¶ 45.

Third, as explained above, Forest's expert also relies upon a "therapeutic effect" to attempt to distinguish the prior art in his validity analysis. Opper Decl. Ex. 38, Farlow Dep., at 210:13-25. It is axiomatic that claims are construed in the same manner for purposes of infringement and validity. *Source Search Techs., LLC v. Lendingtree, LLC*, 588 F.3d 1063, 1075 (Fed. Cir. 2009). Given that Forest's expert is arguing that the claims require a "beneficial therapeutic effect" for purposes of invalidity, Forest has no basis for denying that the claims require precisely the same "therapeutic effect" for purposes of infringement.

Fourth, Forest's citation to Dr. Herrmann's testimony seems to suggest that Dr. Herrmann applied his own "interpretation of the patent" rather than the patent court's claim construction. This is simply false. Dr. Herrmann's report makes explicit that he applied the patent court's claim constructions. Opper Decl. Ex. 27, Herrmann Rpt. ¶ 32. He also repeatedly quoted the patent court's claim construction for "effective amount" (*Id.* ¶¶ 31, 34, 73, 83) and tied his analysis of infringement explicitly to that verbatim construction (*Id.* ¶¶ 78 et seq.).

d) Deposition Page 264

Finally, Forest cites lines 5-19 of page 264. Defs.' Br. at 5. Plaintiffs cannot discern the basis for Forest's complaint from that snippet. To the extent that Forest's complaint is premised on Dr. Herrmann's reference to "therapeutic effect," that has been addressed in detail above. To the extent that Forest is complaining that the term "effective amount" modifies the preamble language, Plaintiffs have addressed that above as well. It cannot refer to anything else, because otherwise the claims are necessarily invalid for improper broadening. *See* Section I.A *supra*.

Forest may, however, be complaining about Dr. Herrmann's view that, to prevail on infringement, "Forest needed to run a placebo-controlled clinical trial to directly measure whether those therapeutic effects that memantine was producing were a result of NMDA receptor antagonism." Lancaster Decl. Ex. 1, Herrmann Dep., at 264:5-11. If so, this is a direct consequence of the claim construction of "effective amount" that Forest successfully argued for in the patent litigation. That construction requires "an amount shown to cause improvement in comparison to placebo," not merely "an amount that causes improvement in comparison to placebo." As a direct result, to establish infringement Forest was required to prove that memantine had been "shown" in a placebo-controlled study to cause improvement in "treating or preventing cerebral ischemia," as that term was construed by the patent court. As Forest's own experts and fact witness have readily admitted, Forest never had – and still does not have – such evidence. Opper Decl. Ex. 41, PX-0460, Doody Dep., at 24:3-8; 25:8-25; 26:3-11; 29:13-20; 30:6-17 (FRX-AT-04579891-893); Opper Decl. Ex. 38, Farlow Dep., at 160:23-164:13; Opper Decl. Ex. 30, PX-1196, Banerjee Dep., at 8:18-21 and 21:23-22:17 (MYLMEMA_006920-924). This is just one of the numerous reasons that Mylan was going to prevail in the Namenda patent litigation.

B. Forest's Motion Is an Untimely *Daubert* Motion

Even if Forest's motion had merit – and it has absolutely none – Forest's motion should be denied as untimely. Under the Third Amended Case Management Order, *Daubert* challenges to expert testimony were due on November 17, 2017. ECF No. 397 at 2. Forest does not even attempt to conceal that its motion is based on Federal Rule of Evidence 702:

Dr. Herrmann's personal opinion on how the patent should have been construed is not "based on sufficient facts or data" as required by Rule 702.

Defs.' Br. at 5; *see also id.* at 2 ("Such an argument could not have been advanced by Mylan at the patent trial if it had occurred, and accordingly, should not be allowed here. *See* Fed. R. Evid. 702 (the purpose of expert testimony is 'to help the trier of fact to understand the evidence or to determine a fact in issue').").

Courts have not been hesitant to deny untimely *Daubert* motions disguised as motions *in limine*. *Hart v. BHH, LLC*, Civ. No. 15-cv-4804, 2019 WL 1494027, at *1 (S.D.N.Y. Apr. 4, 2019) ("But these are classic *Daubert* questions which could have been raised in the first *Daubert* motion. Accordingly, this Court construes Defendants' second motion *in limine* as an untimely *Daubert* motion in violation of this Court's scheduling order or as an untimely motion for reconsideration."). Indeed, as this Court has noted:

As far as this court is concerned, the Parties have waived any *Daubert* arguments by not raising them at summary judgment. *If I can consider an expert's* [testimony] at summary judgment, a jury can consider it at trial.

United States v. Teva Pharm. USA, Inc., Civ. No. 13-cv-3702, 2019 WL 1245656, at *12(S.D.N.Y. Feb. 27, 2019) (McMahon, J.) (emphasis added).

III. CONCLUSION

For the foregoing reasons, Plaintiffs request that this Court deny Forest's MIL No. 12.

Dated: June 14, 2019 Respectfully Submitted:

David F. Sorensen
Ellen T. Noteware
Daniel C. Simons
Nick Urban
Berger Montague PC
1818 Market Street – Suite 3600
Philadelphia, PA 19103
(215) 875-3000
(215) 875-4604 (fax)
dsorensen@bm.net
enoteware@bm.net
dsimons@bm.net
nurban@bm.net

Peter Kohn
Joseph T. Lukens
Faruqi & Faruqi, LLP
1617 John F Kennedy Blvd., Suite 1550
Philadelphia, PA 19103
(215) 277-5770
(215) 277-5771 (fax)
pkohn@faruqilaw.com
jlukens@faruqilaw.com

/s/ Dan Litvin
Bruce E. Gerstein
Joseph Opper
Kimberly M. Hennings
Dan Litvin
Garwin Gerstein & Fisher LLP
88 Pine Street, 10th Floor
New York, NY 10005
Tel: (212) 398-0055
Fax: (212) 764-6620
bgerstein@garwingerstein.com
jopper@garwingerstein.com
khennings@garwingerstein.com

David C. Raphael, Jr. Erin R. Leger Smith Segura & Raphael, LLP 3600 Jackson Street, Suite 111 Alexandria, LA 71303 Tel: (318) 445-4480 Fax: (318) 487-1741 draphael@ssrllp.com eleger@ssrllp.com

dlitvin@garwingerstein.com

Stuart E. Des Roches Andrew W. Kelly Odom & Des Roches, LLC 650 Poydras Street, Suite 2020 New Orleans, LA 70130 Tel: (504) 522-0077 Fax: (504) 522-0078 stuart@odrlaw.com akelly@odrlaw.com

Russ Chorush
Heim Payne & Chorush, LLP
1111 Bagby, Suite 2100
Houston, TX 77002
Tel: (713) 221-2000
Fax: (713) 221-2021
rchorush@hpcllp.com

Counsel for the Direct Purchaser Class Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on June 14, 2019, I electronically filed the above by CM/ECF system.

Respectfully submitted,

/s/ *Dan Litvin*Dan Litvin